UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/932,347	08/17/2001	Daniel M. Ritt	50000-0039	4209

7590 09/09/2004

Matthew J. Russo
Rader, Fishman & Grauer PLLC
Suite 140
383 Inverness Drive South
Englewood, CO 80112

EXAMINER	
JOHNS, ANDREW W	
ART UNIT	PAPER NUMBER
2621	

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/932,347	RITT	
	Examiner	Art Unit	
	Andrew W. Johns	2621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-18 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-18 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 17 August 2001 is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 4/15/02.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. Figure 1 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See M.P.E.P. § 608.02(g). In addition, the characters in Figure 1 are not uniform, clear, and well-formed. See 37. C.F.R. § 1.84(l). Corrected drawings in compliance with 37 C.F.R. § 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 C.F.R. § 1.121(d)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 U.S.C. § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

3. Claims 1-6, 8-10, 14-15 and 17-18 are rejected under 35 U.S.C. § 102(a) as being anticipated by Yorke et al. (Article entitled "Respiratory Gating of Sliding Window IMRT" from the *Proc. of the 22nd Ann. EMBS Int. Conf.*).

With respect to claim 1, Yorke et al. teaches a method of performing quality assurance on an interrupted treatment of radiation therapy (Abstract, lines 2-7; page 2119, first two lines), including measuring a first delivered dose distribution during an uninterrupted treatment (page 2119, third paragraph, lines 2-3; exposure made for normal (i.e., uninterrupted) delivery);

measuring a second delivered dose distribution during an interrupted treatment (page 2119, third paragraph, lines 2-3; separate exposure made for gated (i.e., interrupted) delivery); obtaining first and second images that represent the first and second delivered dose distributions, respectively (page 2119, fourth paragraph, lines 1-2); registering the first and second images so that they substantially map into the same space (page 2119, fourth paragraph, lines 2-3; images aligned and overlayed); and comparing the first and second images to determine any differences between the first and second images (page 2119; fourth paragraph, lines 4-5; differences calculated and displayed). Yorke et al. also teaches displaying a quality characteristic indicating the differences between the first and second images (page 2119; fourth paragraph, lines 4-5; differences calculated and displayed), as further required by claim 2; measuring the first and second delivered dose distributions by exposing a detection medium to radiation from an uninterrupted treatment and from an interrupted treatment, respectively (separate exposures of Kodak XV film are made for normal (uninterrupted) delivery and gated (interrupted) delivery; page 2119, third paragraph, lines 1-3), as additionally stipulated in claim 3; measuring the first and second delivered dose distributions by exposing the detection medium to a test pattern (i.e., slit fields; page 2119, second paragraph, last two lines), as defined in claim 4; or measuring the first and second delivered dose distributions by exposing the detection medium to a treatment plan of a patient (page 2119, second paragraph, lines 3-5), as set forth in claim 5; and obtaining the first and second images by digitizing the first and second delivered dose distributions, respectively (i.e., the films are scanned to form digital images; page 2119, fourth paragraph, line 1), as required by claim 6. Furthermore, Yorke et al. additionally teaches that comparing the first and second images by subtracting the first image from the second image (i.e., Yorke et al. calculates and displays *differences*; page 2119, fourth paragraph, last line), as stipulated in claim 8;

calculating dose area distributions (as shown in Figures 1a and 1b on page 2120; the dose distributions are two-dimensional and thus have an area), as required by claim 9; and subtracting the dose area distributions (page 2119, fourth paragraph, last two lines; the difference is between the distributions), as stipulated by claim 10. Yorke et al. also teaches that the dose area distributions are cumulative (i.e., each exposure represents the cumulative dose for an entire delivery), as additionally required by claims 13 and 14.

With respect to claim 17, Yorke et al. teaches a device for performing quality assurance on an interrupted treatment of radiation therapy (Abstract, lines 2-7; page 2119, first two lines), the device comprising a software routine tangibly embodied on a computer-readable medium and configured to generate a quality characteristic indicating differences between an uninterrupted treatment and an interrupted treatment (page 2119; fourth paragraph, lines 4-5; differences calculated and displayed by *a program*), the software routine generating the quality characteristic from first and second images (page 2119, fourth paragraph, lines 1-2), the first and second images derived, respectively, from measurements of a first delivered dose distribution obtained during an uninterrupted treatment (page 2119, third paragraph, lines 2-3; exposure made for normal (i.e., uninterrupted) delivery) and a second delivered dose distribution obtained during an interrupted treatment (page 2119, third paragraph, lines 2-3; separate exposure made for gated (i.e., interrupted) delivery).

Finally, regarding claim 18, Yorke et al. teaches a system for performing quality assurance on an interrupted treatment of radiation therapy (Abstract, lines 2-7; page 2119, first two lines), the system comprising a computer having a graphical user interface enabling a user to interact with a software routing running on the computer, the software routine configured to generate a quality characteristic indicating differences between an uninterrupted treatment and an

interrupted treatment (page 2119; fourth paragraph, lines 4-5; differences calculated and displayed by *a program*, which inherently runs on a computer which conventionally includes a graphical user interface), the software routine generating the quality characteristic from first and second images (page 2119, fourth paragraph, lines 1-2), the first and second images derived, respectively, from measurements of a first delivered dose distribution obtained during an uninterrupted treatment (page 2119, third paragraph, lines 2-3; exposure made for normal (i.e., uninterrupted) delivery) and a second delivered dose distribution obtained during an interrupted treatment (page 2119, third paragraph, lines 2-3; separate exposure made for gated (i.e., interrupted) delivery).

Claim Rejections - 35 U.S.C. § 103

4. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claim 7 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Yorke et al. as applied to claims 1-6, 8-10, 13-14 and 17-18 above, and further in view of Takeo et al. (US 6,563,942 B2).

While Yorke et al. meets a number of the limitations of the claimed invention, as pointed out more fully above, Yorke et al. fails to specifically teach using an AFFINE transform to register the first and second images, as additionally required by claim 7.

However, the use of Affine transforms in general is well-known, and more specifically, Takeo et al. teaches using an affine transform to register or align a plurality of radiation images

(see the Abstract, for example). Since Takeo et al. teaches that this use of the affine transform provides higher accuracy in positional adjustments based on the images (column 7, lines 35-41), it would have been obvious to one of ordinary skill in the art to use the affine transform to register the images in Yorke et al. to minimize alignment errors in the calculated differences, resulting in more accurate measurement of the quality of the interrupted radiation therapy.

6. Claims 11-12 and 15-16 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Yorke et al. as applied to claims 1-6, 8-10, 13-14 and 17-18 above, and further in view of Robar et al. (US 6,668,073 B1).

While Yorke et al. meets a number of the limitations of the claimed invention, as pointed out more fully above, Yorke et al. fails to specifically teach calculating volume or cumulative volume distributions, as variously required by claims 11-12 and 15-16. The single film exposed during each treatment only provides an area distribution. However, the tumors treated by the radiation therapy are three-dimensional, so a more accurate quality assessment would be obtained if volume distributions were measured.

Robar et al. teaches the use of a plurality of films, simultaneously exposed, that provide a three-dimensional (i.e., volume) dose distribution measurement (Abstract, lines 14-23). Because Robar et al. suggests that such volume dose distribution measurements can improve the quality of treatment (Abstract, lines 25-28), it would have been obvious to one of ordinary skill in the art to use such volume distribution measurements in the Yorke et al. system to provide a more accurate quality assessment.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew Johns whose telephone number is (703) 305-4788. The examiner in normally available Monday through Friday, at least during the hours of 9:00 am to

3:00 pm Eastern Time. The examiner may also be contacted by e-mail using the address: andrew.johns@uspto.gov. (Applicant is reminded of the Office policy regarding e-mail communications. See M.P.E.P. § 502.03)

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Leo Boudreau, can be reached on (703) 305-4706. The fax phone number for this art unit is (703) 872-9306. In order to ensure prompt delivery to the examiner, all unofficial communications should be clearly labeled as "Draft" or "Unofficial."

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center Receptionist whose telephone number is (703) 305-4700.

A. Johns
31 August 2004